REMARKS

Claims 1, 4-9 and 12-16 are pending and stand rejected. The Examiner has made formal rejections of the claims pursuant to 35 U.S.C. 112. Claims have also been rejected based on Donson ('931 patent) and Untermohlen ('976 patent). In addition, the Examiner has raised double patenting rejections for certain claims.

A. Formal Rejections

The Examiner rejects Claims 1, 4-9 and 12-16 under 35 U.S.C. 112 as allegedly indefinite. The term "in" is argued to be indefinite, but the Examiner indicates "into" would remedy the alleged defect. Without acquiescing to the rejection, but to further the prosecution, the claims have been amended in the manner suggested by the Examiner. The right to prosecute the unamended claims (or similar claims) in the future is expressly hereby reserved.

The Examiner also argued that the source of the assembled virus is unclear. While not agreeing with the rejection, but to further the prosecution, the claims have been amended to indicate even more clearly that the source of the assembled virus is the modified nucleic acid. The right to prosecute the unamended claims (or similar claims) in the future is expressly hereby reserved.

While not a formal 112 rejection, the Examiner argues that the use of the term "native" in the claims is subject to an interpretation that "is not exclusive to insertion into *native* functional coat protein." (Office Action, page 4). The Examiner goes on to use this interpretation in making rejections. While it is not at all clear how the Examiner reaches this interpretation (let alone how the Examiner justifies it as "reasonable"), the claims have been amended to indicate that the insertion is "an addition to the existing nucleic acid" (as indicated for one embodiment in the specification at page 5, first full paragraph). The amendments have been made without acquiescing to the rejection, but to further the prosecution, and the right to prosecute the unamended claims (or similar claims) in the future is expressly hereby reserved.

B. The Examiner Use Of the '931 Patent Is Not Supported

The Examiner has, once again, asserted the '931 patent. Importantly, the Examiner has not addressed ALL of the arguments and supporting quotes from the parent specification. Instead, the Examiner has ignored the broad teachings in the parent specification in favor of a narrow unreasonable interpretation.

In a prior response, the Examiner was asked to look carefully at the passages in the parent specification. Nonetheless, the Examiner does not address the meaning of passages such as the one on page 11, lines 27-35 (lines 27-32 are shown below):

> "The first step in achieving any of the features of the invention is to modify the nucleotide sequences coding for the capsid protein and any transmissibility factors within the viral nucleotide sequence by known conventional techniques such that non-biologically functional proteins are produced by the modified virus."

Is this not a clear statement that non-biologically functional proteins are intended for achieving ANY of the features of the invention? This was argued before to the Examiner. Where is the Examiner's response to this? Apparently, the Examiner has ignored this clear teaching.

The Examiner also apparently elects to ignore the passage at page 25, lines 13-35 (lines 13-27 are shown below):

> "The nucleotide sequence of any suitable virus can be derived from a viral nucleic acid by modifying the coat protein coding sequence. The modification may be the removal of a coding sequence for at least a part of the viral coat protein. Alternatively, the nucleotide sequence can be synthesized such that it lacks at least a part of the viral coat protein coding sequence. A sufficient amount of the coding sequence is removed such that any coat protein which may be produced by the virus will be incapable of encapsidating the viral nucleic acid. In addition, the coat protein coding sequence may be modified by mutation such that the coat protein which is produced is incapable of encapsidating the viral nucleic acid. In each instance, as non-biologically functional protein is produced."

This passage - even more clearly than the first - teaches the deletion or alteration of the coat protein to destroy function.

In the prior response, a side-by-side was presented. It was argued that the parent specification (right hand side, italics) teaches *deleting the coding sequence* for the plant viral coat

protein or *altering the native sequence.* It is only in the context of the ALTERED sequence that *insertion* is discussed. Oddly, the Examiner seizes on the term "fusion protein" in the paragraph as a basis for arguing: "One of skill in the art would recognize that fusion protein means the foreign nucleotide sequence is inserted into the viral genomic sequence" and then argues that "the fusion protein may have biological activity (i.e. functionality)." (Office Action, p. 6)

The Examiner must take note, however, that the paragraph (which contains the "fusion protein" term) begins "In those instances where the coat protein coding sequence is *altered* but not deleted . ." This language is consistent with the earlier-quoted language (see above) that provides the teaching to either DELETE or MODIFY (altered being another word for modify). The earlier-quoted passage further indicates that, if MODIFICATION is used, "the coat protein coding sequence may be modified by mutation such that the coat protein which is produced is incapable of encapsidating the viral nucleic acid."

What is the Examiner's response to this? It is a single, conclusory sentence: "However, this interpretation is simply not borne out of what is disclosed in the '244 application." (Office Action, page 6). This is improper examination. The Examiner provides NO evidence in support of a contrary interpretation. The Examiner simply *argues* "functionality" - BUT CAN POINT TO NO PASSAGE WHICH USES THIS TERM!

The Examiner is reminded that the MPEP requires *evidence* to support argument. Naked assertions by the Examiner are not *evidence.* Waiving ones hands and saying "totality" is not evidence.

Importantly, the side-by-side establishes that the specification of the '931 was changed and that the '931 patent contains new matter. Thus, it does not enjoy the filing date of the parent. Thus, the passage cannot be used as a basis for rejection. Since no other passages are offered by the Examiner to show a teaching for the insertion of the foreign peptide into the coat protein, the rejection based on the '931 specification cannot stand.

C. The Obviousness Rejection Must Fail

The Examiner makes an obviousness rejection based on a combination of the '931 patent with Untermohlen (the '976 patent). However, as shown above, the '931 patent cannot be combined with anything - it is not prior art.

D. Double Patenting

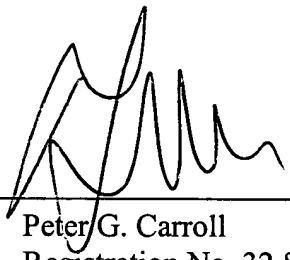
The Examiner has rejected Claims 9 and 12-16 under the judicially created doctrine of double patenting over claims 1-9 of U.S. Patent 5,874,087 stating that the claims are not patentably distinct over the claims of the '087. The Applicants respectfully disagree.

Nonetheless, provided Applicants' claims are otherwise found allowable, Applicants may split out these claims into a separate application with the required Terminal Disclaimer. This would permit Claims 1-8 to issue. The Examiner is requested to call the undersigned prior to another Office Action in order to discuss this procedure.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that these grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617-984-0616.

Dated: December 13, 2004



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